Bayer

201-14975

Bayer Corporation
100 Bayer Road
Pittsburgh, PA 15205-9741
Phone: 412 777-2000

December 29, 2003

Administrator Michael O. Leavitt
U.S. Environmental Protection Agency
c/o P.O. Box 1473
Merrifield, VA 22116

RECEIVED
OPPT CBIC
03 DEC 31 AM 10: 28

Attn: Chemical Right-to-Know Program
Re: HPV Registration No.
1-Naphthalenamine, N-phenyl- (CAS# 90-30-2)

Dear Administrator Leavitt;

The chemical N-phenyl-1-Naphthalenamine was originally sponsored by Bayer Chemicals LLC, who has since stopped the manufacture of the product. Subsequently, Bayer CropScience LP has begun manufacturing this material and agrees to sponsor this chemical in the HPV Chemical Program. Bayer CropScience LP is pleased to submit the proposed test plan along with the robust summaries in IUCLID format for N-phenyl-1-Naphthalenamine (CAS# 90-30-2).

Cynthia Graham, Ph.D. is our technical contact and can be reached at 412-777-3933 or by email at cynthia.graham@bayerpolymers.com .

This submission is also being sent electronically to the following e-mail addresses: Oppt.ncic@epa.gov; Chem.rtk@epa.gov.

Sincerely,

Janet M. Mostowy, Ph.D.
Vice President
Product Safety & Regulatory Affairs

Enclosures:
Test Plan and IUCLID data set on CAS# 90-30-2

cc: Rich Hefter, EPA
Karen Hoffman, EPA
Oscar Hernandez, EPA
Pat Ragan, Bayer CropScience
Mike Wey, Bayer CropScience

201-14975B

1-Naphthalenamine, N-phenyl-

CAS # 90-30-2

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HPV Test plan

Bayer CropScience LP

December 29, 2003

Executive Summary

Bayer CropScience LP (Bayer) hereby submits for review and public comment their test plan for 1-Naphthalenamine, N-phenyl- (N-Phenyl-alpha-Naphthylamine, CAS# 90-30-2) under the Environmental Protection Agency's High Production Volume (HPV) Chemical Challenge Program.

IUPAC Name	Common Name	CAS#
1-Naphthalenamine, N-phenyl-	PANA	90-30-2

PANA is used in jet engine lubricants, both for commercial and military uses. It is also used in turbine oils and miscellaneous lubricants and greases. Small quantities are used to make polymers which are then used in lubricants, and for consumption into rubber industry.

In consideration of animal welfare concerns to minimize the use of animals in the testing of chemicals, Bayer has conducted a thorough literature search for all available data, published and unpublished. It has also performed an analysis of the adequacy of the existing data. Existing data indicates that this chemical is of high concern for aquatic toxicity, low concern as Persistent Organic Pollutants (POP), low concern for skin and eye irritation, and low concern for acute mammalian toxicity. There were no fertility or developmental studies found, but there is a repeated dose, carcinogenicity study in mice demonstrating lung and kidney tumors. PANA does contain trace amounts of 2-naphthylamine (Beta-naphthylamine, CAS# 91-59-8) which has been given a carcinogenicity designation of "A1-Confirmed human carcinogen" by the American Conference of Governmental Industrial Hygienists (ACGIH). Since exposure is controlled to avoid the risk of carcinogenicity, additional animal testing would not provide useful or relevant data for risk assessment. No additional testing of PANA is proposed for purposes of the HPV Program.

Data Review

Physicochemical properties:

The properties of PANA were available from internal studies and Chemical Dictionary Handbooks. PANA is solid at ambient temperatures and has a melting point of 62-63ºC and boiling point of 226ºC @ 20hPa. Vapor pressure is less than 0.1 hPa at temperatures from 20 -123ºC. The measured octanol/water partition coefficient is 4.28 and PANA is of very low solubility in water (3 mg/l at 20 °C). Data is available for all endpoints, no additional testing is proposed for purposes of the HPV Program (See Table 1 and IUCLID document).

Environmental Fate:

Photodegradation of PANA was measured at 79% degradation after 12 minute(s). Fugacity modeling demonstrates partitioning to the soil (66.3%) and water (27.7%) compartments. There is monitoring data showing ppb levels in manufacturing effluent and low levels in river sediment. Aerobic biodegradation testing demonstrated that PANA did not biodegrade after 28 days under test conditions. A water stability study demonstrated that PANA, in aqueous solution, was eliminated by 48- 55% within 34 days. Several bioaccumulation studies have also been performed using PANA. The BCF in *Cyprinus carpio* (56 days) was 427-2730 (at 0.1 mg/l) and 889-2490 (at 0.01 mg/l). In Lepomis macrochirus (10 days at 0.03 mg/l), the BCF based on total 14C residues were 1111 for whole fish, 627 for edible fish and 3820 for viscera. Data is available for all endpoints, no additional testing is proposed for purposes of the HPV Program (See Table 1 and IUCLID document).

Ecotoxicology:

Several aquatic studies have been done. LC_{50} results of 7.9 mg/l (48 hr, *Oryzias latipes*) and 0.47 mg/l (8 day, *Lepomis macrochirus*) were demonstrated in two of the studies. An EC_{50} of 0.68 mg/l (48 hr, *Daphnia*) and a chronic invertebrate EC50 of 0.06mg/l *(*21 day*, Daphnia)* indicate that PANA is toxic to aquatic organisms. Since PANA is toxic to the aquatic environment, acute toxicity to Algae would not supply useful or relevant data for risk assessment. No additional testing is proposed for purposes of the HPV Program (See Table 1 and IUCLID document).

Mammalian Toxicology:

Toxicity studies in animals show that PANA is of low acute toxicity by the oral and dermal routes of exposure: oral LD_{50} >5000 mg/kg (male and female rat) and dermal LD_{50} > 5000 mg/kg (rabbit). (See Table 1 and IUCLID document for more detail).

There are many studies testing the mutagenicity of PANA. There are bacterial gene mutation assays using *Salmonella typhimurium*, *Escherichia coli* and *Saccharomyces cerevisiae*, all with negative results. There are *in vitro* Mammalian Cytogenetic assays using Chinese hamster ovary (CHO) cells and Chinese hamster lung cells, both demonstrating negative results. There is also a Sister chromatid exchange assay in CHO cells and an "Unscheduled DNA synthesis" assay using WI-38 cells, both with ambiguous results. However an *in vivo* Dominant lethal assay in male mice demonstrated a negative result. Data is available for the mutagenicity endpoints, no additional testing is proposed for purposes of the HPV Program (See Table 1 and IUCLID document).

A repeated oral dose study in dogs for 36-42 months demonstrated a NOAEL of 290 mg/kg body weight. There were no fertility or developmental studies found. PANA contains trace amounts of an impurity known to be carcinogenic. Since exposure is controlled to avoid the risk of carcinogenicity, additional animal testing would not provide useful or relevant data for risk assessment. For that reason no testing is proposed for purposes of the HPV Program. (See Table 1 and IUCLID document).

"Beyond SIDS" Endpoints:

Studies have been performed with PANA to investigate skin and eye irritation and were found to be slightly irritating to the skin and non-irritating to the eyes of rabbits. PANA was found to be a dermal sensitizer in guineas pigs.

An oral dose carcinogenicity study has been performed on dogs for 36-42 months with negative results. There is also a carcinogenicity study on mice using sub-cutaneous exposure. Exposure of 262 -295 days showed lung and kidney tumors. However, a critical evaluation by European governing bodies has concluded that there is not sufficient evidence to classify PANA as a carcinogen. (See Table 2 and IUCLID document).

Exposure considerations

During the processing, PANA is a liquid with a relatively low vapor pressure and is handled in a closed system. There are minimal exposure concerns. Employees wear long sleeved shirts, chemical-resistant gloves when appropriate, and safety glasses.

During the drumming of PANA, drums are filled in a ventilated enclosure, and again there are minimal exposure concerns. Employees wear long sleeved shirts, chemical-resistant gloves when appropriate, and safety glasses.

PANA drums are processed so the material can be placed in bags by a third party. Employees at the location utilize respiratory and skin protection to ensure that potential exposures are minimized. Therefore during processing and packaging, with engineering controls and personal protection equipment, exposure is negligible.

Due to the fact that PANA is a small quantity component in formulations used by downstream customers, it is believed that all potential exposures would also be negligible.

Conclusion

Existing data indicates that this chemical is of high concern for aquatic toxicity, low concern as Persistent Organic Pollutants (POP), low concern for skin and eye irritation, and low concern for acute mammalian toxicity. There were no fertility or developmental studies found, but there is a repeated dose, carcinogenicity study in mice demonstrating lung and kidney tumors. PANA does contain trace amounts of 2-naphthylamine (Beta-naphthylamine, CAS# 91-59-8) which has been given a carcinogenicity designation of "A1-Confirmed human carcinogen" by the American Conference of Governmental Industrial Hygienists (ACGIH). Since exposure is controlled to avoid the risk of carcinogenicity, additional animal testing would not provide useful or relevant data for risk assessment. No additional testing of PANA is proposed for purposes of the HPV Program.

Table 1. Available data for PANA (CAS# 66346-01-8)

Endpoint	PANA
Physical-Chemical Data	
Molecular weight	219.29
Physical state	solid
Melting Point	62-63 ºC
Boiling Point	226 ºC @ 20 hPa
Vapor Pressure	< 0.1 hPa
Partition Coefficient ($logP_{ow}$)	4.28
Water Solubility	3 mg/l at 20 °C
Environmental Fate	
Photodegradation	T ½ = < 12 minutes
Fugacity (distribution)	Air: .05 % Water: 27.7% Soil: 66.3 % Sediment: 5.9 %
Biodegradability	0 % after 28 day(s)
Water Stability	48 - 55 % after 34 day(s)
Ecotoxicology	
Acute Fish Toxicity 48hrs LC_{50}	7.9 mg/l (*Oryzias latipes*)
Acute Invertebrate Toxicity 48 hrs EC_{50}	0.68 mg/l (*Daphnia magna*)
Algal Toxicity 96 hrs LC_{50}	No data
Mammalian Toxicology	
Acute Toxicity	LD_{50} > 5000 mg/kg bw (oral, male/female rats) LD_{50} > 5000 mg/kg bw (dermal, rabbit)
Mutagenicity	Ames = negative
Chromosome Aberration	Cytogenetic assay = negative (CHO cells and CHL cells) Dominant lethal = negative (*in vivo*, mouse)
Repeated Dose Toxicity	NOAEL = 290 mg/kg bw (oral, dog, 36-42 months)
Reproductive Toxicity	No data
Developmental Toxicity	No data

* Robust summaries and References can be found in the IUCLID document.

Table 2. "Beyond SIDS" data for PANA (CAS# 66346-01-8)

Endpoint	PANA
Ecotoxicology	
Sub-acute Fish Toxicity 8 days LC_{50}	0.46 - 0.48 mg/l (*Lepomis macrochirus*) 0.3 mg/l (*Oncorhynchus mykiss*)
Chronic Invertebrate Toxicity 21 days EC_{50}	0.06 mg/l (*Daphnia magna*)
Mammalian Toxicology	
Skin Irritation	Slightly irritating (rabbit)
Eye Irritation	Not irritating (rabbit)
Sensitization	Sensitizing (guinea pig)
Carcinogenicity	Negative (oral, dog, 36-42 months) Lung and kidney tumors but no dose response (sub-cutaneous, mouse)

* Robust summaries and References can be found in the IUCLID document.

Table 3. Test Plan for PANA (CAS# 66346-01-8)

Endpoint	Data Availability	Acceptable	Planned testing
Physical-Chemical Data			
Melting Point	✓	✓	
Boiling Point	✓	✓	
Vapor Pressure	✓	✓	
Partition Coefficient ($logP_{ow}$)	✓	✓	
Water Solubility	✓	✓	
Environmental Fate			
Photodegradation	✓	✓	
Fugacity	✓	✓	
Biodegradability	✓	✓	
Water Stability	✓	✓	
Ecotoxicology			
Acute Fish Toxicity	✓	✓	
Acute Invertebrate Toxicity	✓	✓	
Algal Toxicity			**Derogation statement**
Mammalian Toxicology			
Acute Toxicity	✓	✓	
Mutagenicity	✓	✓	
Chromosome Aberration	✓	✓	
Repeated Dose Toxicity	✓	✓	
Reproductive Toxicity			**Derogation statement**
Developmental Toxicity			**Derogation statement**

✓ = data available and considered adequate.

Bayer

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Attn: Chemical Right-to-Know Program
Re: HPV Registration No.
1-Naphthalenamine, N-phenyl- (CAS# 90-30-2)

Dear Administrator Leavitt;

The chemical N-phenyl-1-Naphthalenamine was originally sponsored by Bayer Chemicals LLC, who has since stopped the manufacture of the product. Subsequently, Bayer CropScience LP has begun manufacturing this material and agrees to sponsor this chemical in the HPV Chemical Program. Bayer CropScience LP is pleased to submit the proposed test plan along with the robust summaries in IUCLID format for N-phenyl-1-Naphthalenamine (CAS# 90-30-2).

Cynthia Graham, Ph.D. is our technical contact and can be reached at 412-777-3933 or by email at cynthia.graham@bayerpolymers.com .

This submission is also being sent electronically to the following e-mail addresses: Oppt.ncic@epa.gov; Chem.rtk@epa.gov.

Sincerely,

Janet M. Mostowy, Ph.D.
Vice President
Product Safety & Regulatory Affairs

Enclosures:
Test Plan and IUCLID data set on CAS# 90-30-2

cc: Rich Hefter, EPA
Karen Hoffman, EPA
Oscar Hernandez, EPA
Pat Ragan, Bayer CropScience
Mike Wey, Bayer CropScience

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I U C L I D

Data Set

Existing Chemical	:	ID: 90-30-2
CAS No.	:	90-30-2
EINECS Name	:	N-1-naphthylaniline
EC No.	:	201-983-0
TSCA Name	:	1-Naphthalenamine, N-phenyl-
Molecular Formula	:	C16H13N

Producer related part

Company	:	Bayer Corporation
Creation date	:	15.07.1999

Substance related part

Company	:	Bayer Corporation
Creation date	:	15.07.1999
Status	:	
Memo	:	Bayer CropScience LLC
Printing date	:	18.12.2003
Revision date	:	
Date of last update	:	18.12.2003
Number of pages	:	50
Chapter (profile)	:	Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
Flags (profile)	:	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 APPLICANT AND COMPANY INFORMATION

Type	:	manufacturer
Name	:	Bayer Corporation
Contact person	:	
Date	:	
Street	:	100 Bayer Road
Town	:	PA 15205-9741 Pittsburgh
Country	:	United States
Phone	:	
Telefax	:	
Telex	:	
Cedex	:	
Email	:	
Homepage	:	

18.12.2003

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

IUPAC Name	:	1-(N-Phenylamino)naphthalene
Smiles Code	:	N(c(c(c(ccc1)cc2)c1)c2)c(cccc3)c3
Molecular formula	:	C16 H13 N1
Molecular weight	:	219.29
Petrol class	:	

18.12.2003

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type	:	typical for marketed substance
Substance type	:	organic
Physical status	:	solid
Purity	:	>= 99 % w/w
Colour	:	tan
Odour	:	weak pungent naphthol odor
Source	:	Bayer CropScience LLC

18.12.2003

1.1.2 SPECTRA

1.2 SYNONYMS AND TRADENAMES

N-phenyl-1-naphthylamine

18.12.2003

N-phenyl-alpha-naphthylamine

18.12.2003

PANA

18.12.2003

1.3 IMPURITIES

Purity : typical for marketed substance
CAS-No : 134-32-7
EC-No :
EINECS-Name : 1-Naphthalenamine
Molecular formula :
Value : < .05 % w/w

18.12.2003

Purity : typical for marketed substance
CAS-No : 135-88-6
EC-No : 205-223-9
EINECS-Name : N-2-naphthylaniline
Molecular formula :
Value : < .5 % w/w

18.12.2003

Purity : typical for marketed substance
CAS-No : 62-53-3
EC-No :
EINECS-Name : Benzenamine
Molecular formula :
Value : < .25 % w/w

18.12.2003

Purity : typical for marketed substance
CAS-No : 90-15-3
EC-No : 201-969-4
EINECS-Name : 1-naphthol
Molecular formula :
Value : < .5 % w/w

18.12.2003

Purity : typical for marketed substance
CAS-No : 91-59-8
EC-No : 202-080-4
EINECS-Name : 2-naphthylamine
Molecular formula :
Value : < .005 % w/w

18.12.2003

Purity	:	typical for marketed substance
CAS-No	:	
EC-No	:	
EINECS-Name	:	
Molecular formula	:	
Value	:	
Remark	:	cyclohexane insolubles < 0.25 % w/w

18.12.2003

1.4 ADDITIVES

1.5 TOTAL QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.6.3 PACKAGING

1.7 USE PATTERN

1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

1.8 REGULATORY MEASURES

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

1.8.4 MAJOR ACCIDENT HAZARDS

1.8.5 AIR POLLUTION

1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

1.9.2 COMPONENTS

1.10 SOURCE OF EXPOSURE

1.11 ADDITIONAL REMARKS

1.12 LAST LITERATURE SEARCH

1.13 REVIEWS

2.1 MELTING POINT

Value	:	62 - 63 °C
Decomposition	:	no
Sublimation	:	no
Method	:	other: Handbook value
Year	:	
GLP	:	no data
Test substance	:	other TS: N-phenyl-1-Naphthalenamine, CAS# 90-30-2; purity not noted
Source	:	Bayer AG Leverkusen Data from Handbook or collection of data.
Flag	:	Critical study for SIDS endpoint

18.12.2003 (1) (2)

Value	:	52.5 °C
Decomposition	:	no
Sublimation	:	no
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (3)

2.2 BOILING POINT

Value	:	335 °C at 346.6 hPa
Decomposition	:	
Method	:	other: Handbook value
Year	:	
GLP	:	no data
Test substance	:	other TS: N-phenyl-1-Naphthalenamine, CAS# 90-30-2; purity not noted
Reliability	:	(2) valid with restrictions Data from Handbook or collection of data.
Flag	:	Critical study for SIDS endpoint

18.12.2003 (2)

Value	:	226 °C at 20 hPa
Decomposition	:	no
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (3)

2.3 DENSITY

Type : density
Value : 1.1 - 1.2 g/cm^3 at 20 °C
Method :
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Source : Bayer AG Leverkusen
Reliability : (2) valid with restrictions
Meets generally accepted scientific standards
18.12.2003 (3)

Type : density
Value : 1.16 g/cm^3 at °C
Method :
Year :
GLP : no data
Test substance :

Source : Bayer AG Leverkusen
07.03.1994 (4)

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value : .0000106 hPa at 20 °C
Decomposition :
Method :
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Source : Bayer AG Leverkusen
Reliability : (2) valid with restrictions
Meets generally accepted scientific standards
Flag : Critical study for SIDS endpoint
18.12.2003 (3)

Value : .07 hPa at 123 °C
Decomposition :
Method :
Year :
GLP : no data
Test substance : other TS: N-phenyl-1-Naphthalenamine, CAS# 90-30-2; purity not noted

Source : Bayer AG Leverkusen
Meets generally accepted scientific standards
18.12.2003 (5)

Value : .882 hPa at 160 °C
Decomposition :
Method :
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Source : Bayer AG Leverkusen

18.12.2003 (3)

Value : 20 hPa at 226 °C
Decomposition :
Method :
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Source : Bayer AG Leverkusen
18.12.2003 (3)

2.5 PARTITION COEFFICIENT

Partition coefficient : octanol-water
Log pow : 4.28
Method : other (measured)
Year :
GLP : no data
Test substance : other TS: N-phenyl-1-Naphthalenamine, CAS# 90-30-2; purity not noted

Source : Bayer AG Leverkusen
Reliability : (2) valid with restrictions
Meets generally accepted scientific standards
Flag : Critical study for SIDS endpoint
18.12.2003 (6)

Partition coefficient : octanol-water
Log pow : 4.228
Method : other (measured)
Year :
GLP : no data
Test substance :

Source : Bayer AG Leverkusen
Meets generally accepted scientific standards
18.12.2003 (7)

Partition coefficient : octanol-water
Log pow : 4.2
Method : other (measured)
Year :
GLP : no data
Test substance :

Source : Bayer AG Leverkusen
18.12.2003 (8)

Partition coefficient : octanol-water
Log pow : 4.8
Method : other (calculated): CLOGP Vers. 3.54
Year : 1989
GLP : no
Test substance : other TS: molecular structure of N-phenyl-1-Naphthalenamine, CAS# 90-30-2

Source : Bayer AG Leverkusen
Reliability : (2) valid with restrictions
Accepted calculation method

18.12.2003 (3)

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in	:	Water
Value	:	.003 g/l at 20 °C
pH value	:	7.9 - 8
concentration	:	.003 g/l at 20 °C
Description	:	of very low solubility
Method	:	Directive 84/449/EEC, A.6
Year	:	1984
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

Source	:	Bayer AG Leverkusen
Reliability	:	(1) valid without restriction GLP guideline study
Flag	:	Critical study for SIDS endpoint

18.12.2003 (3)

Solubility in	:	Water
Value	:	.06 g/l at 20 °C
Description	:	of very low solubility
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	other TS: N-phenyl-1-Naphthalenamine, CAS# 90-30-2; purity not noted

Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (6)

Solubility in	:	
Value	:	.00276 g/l at 17 °C
Description	:	of very low solubility
Method	:	
Year	:	
GLP	:	no data
Test substance	:	

Source	:	Bayer AG Leverkusen

18.12.2003 (9)

Solubility in	:	
Value	:	.00192 g/l at 5 °C
Description	:	of very low solubility
Method	:	
Year	:	
GLP	:	no data
Test substance	:	

Source	:	Bayer AG Leverkusen

18.12.2003 (9)

Solubility in	:	
Value	:	.0052 g/l at 35 °C
Description	:	of very low solubility
Method	:	
Year	:	

GLP : no data
Test substance :

Source : Bayer AG Leverkusen
18.12.2003 (9) (10)

pKa : 4.93 at 25 °C

Source : Bayer AG Leverkusen
18.12.2003 (11)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

Value : > 200 °C
Type :
Method :
Year :
GLP : no data
Test substance :

Source : Bayer AG Leverkusen
24.02.1994 (3)

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 DISSOCIATION CONSTANT

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

Remark : Henry's law constant: 0.07748 (Pa x m3/mol)
Source : Bayer AG Leverkusen
25.02.1994 (3)

Remark : Good solubility in most organic solvents (e.g. benzene, methylene chloride, acetone and ethanol); soluble in petrol
Source : Bayer AG Leverkusen
24.02.1994 (4) (12) (13)

3.1.1 PHOTODEGRADATION

Type	:	water
Light source	:	Sun light
Light spectrum	:	300 nm
DIRECT PHOTOLYSIS		
Halflife t1/2	:	ca. 5.7 - 8.4 minute(s)
Degradation	:	ca. 79 % after 12 minute(s)
Quantum yield	:	
Deg. product	:	
Method	:	other (measured): HPLC
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards
Flag	:	Critical study for SIDS endpoint

18.12.2003 (7)

3.1.2 STABILITY IN WATER

Type	:	abiotic
Degradation	:	48 - 55 % after 34 day(s)
Deg. product	:	
Method	:	other: HPLC
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	In aqueous solution, an initial concentration of 582 ug/l was eliminated by 55 and 48 % within 34 d (tube 1 and 2; HPLC-analysis); 22 % decrease of radioactivity (initial concentrations: 871 and 730 ug/l 14C-PAN) after 24 d was attributed completely to adsorption.
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards
Flag	:	Critical study for SIDS endpoint

18.12.2003 (7)

3.1.3 STABILITY IN SOIL

Type	:	laboratory
Radiolabel	:	yes
Concentration	:	1.54 mg/kg
Soil temperature	:	26 °C
Soil humidity	:	
Soil classification	:	other
Year	:	
Deg. product	:	
Method	:	other: HPLC, GLC, MS and liquid scintillation spectrometer
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4

Remark	:	Stability of 1.54 mg 14C-PAN/kg in soil samples (pH 7; 2.3 % organic matter; 75 % field capacity) and of 0.77 mg 14C-PAN/l in soil suspensions was examined.
Result	:	Soil samples: after 2 days of incubation 7% and after 11 days nearly 17% of the initial radioactivity was recovered as 14CO2. Soil suspension: after 2 days 17% and after 11 days 35% of the initial radioactivity were recovered as 14CO2; after 10 days of incubation 95% of the initial PAN were found metabolized and 5% non-metabolized; addition of nutrient broth decreased evolution of 14CO2 in soil and soil suspensions.
Source	:	Bayer AG Leverkusen
Test condition	:	temperature: 26 degree C; dark

18.12.2003 (14)

3.2.1 MONITORING DATA

Type of measurement	:	concentration at contaminated site
Media	:	surface water
Method	:	GC/MS and HRMS analysis
Result	:	Below a wastewater effluent of a chemicals manufacturing plant PAN-concentrations of 2 - 7 ug/l were detected in river water.
Source	:	Bayer AG Leverkusen

18.12.2003 (15) (16)

Type of measurement	:	concentration at contaminated site
Media	:	sediment
Method	:	GC/MS and HRMS analysis
Result	:	Below a waste water effluent of a chemicals manufacturing plant PAN-concentrations of 1 - 5 mg/kg were detected in river sediment.
Source	:	Bayer AG Leverkusen

18.12.2003 (15) (16)

Type of measurement	:	concentration at contaminated site
Media	:	biota
Method	:	
Result	:	In fish obtained from locations near dye or textile manufacturing plants no PAN was detected (detection limit: 1-20 ug/kg).
Source	:	Bayer AG Leverkusen

18.12.2003 (17)

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type	:	fugacity model level III
Media	:	other: air - water - soil - sediment
Method	:	other: Level III Fugacity Model
Year	:	2000
Remark	:	Modeling was performed using equal releases (300 kg/hr) and equal distribution to all compartments.

Result : Level III Fugacity Model (Full-Output):
==========

Chem Name : 1-Naphthalenamine, N-phenyl-
Molecular Wt: 219.29
Henry's LC : 1.03e-007 atm-m3/mole (Henrywin program)
Vapor Press : 0.0504 mm Hg (Mpbpwin program)
Liquid VP : 0.0943 mm Hg (super-cooled)
Melting Pt : 52.5 deg C (user-entered)
Log Kow : 4.2 (user-entered)
Soil Koc : 6.5e+003 (calc by model)

	Mass Amount (%)	Half-Life (hr)	Emissions (kg/hr)
Air	0.0515	0.741	300
Water	27.7	900	300
Soil	66.3	900	300
Sediment	5.93	3.6e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (%)	Advection (%)
Air	3.44e-013	289	3.09	32.1	0.343
Water	3.86e-013	128	166	14.2	18.4
Soil	6.64e-014	306	0	34	0
Sediment	2.66e-013	6.84	0.711	0.76	0.079

Persistence Time: 666 hr
Reaction Time: 821 hr
Advection Time: 3.53e+003 hr
Percent Reacted: 81.1
Percent Advected: 18.9

Reliability : (2) valid with restrictions
Accepted calculation method

Flag : Critical study for SIDS endpoint

18.12.2003 (18)

3.3.2 DISTRIBUTION

Media : air - biota - sediment(s) - soil - water
Method : Calculation according Mackay, Level I
Year :

Result : air: 0.78 %
water: 28.98 %
soil: 36.29 %
sediment: 33.87 %
susp. sediment: 0.06 %
biota: 0.02 %

Source : Bayer AG Leverkusen
Reliability : (2) valid with restrictions
Accepted calculation method

18.12.2003 (19)

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type	:	aerobic
Inoculum	:	activated sludge, non-adapted
Concentration	:	100 mg/l related to Test substance related to
Contact time	:	
Degradation	:	0 (±) % after 28 day(s)
Result	:	under test conditions no biodegradation observed
Deg. product	:	
Method	:	OECD Guide-line 301 C "Ready Biodegradability: Modified MITI Test (I)"
Year	:	1981
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Bayer AG Leverkusen
Reliability	:	(1) valid without restriction GLP guideline study
Flag	:	Critical study for SIDS endpoint

18.12.2003 (3)

Type	:	aerobic
Inoculum	:	other
Concentration	:	2 mg/l related to Test substance
Method	:	other: batch tests with primary domestic sewage effluent and lake water; HPLC-analysis
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Sewage effluent: assuming first order kinetics the degradation rate constant was 0.0068 h/l (after a lag period of ca. 4.2 d) and the half life 4.2 days; 3 % PAN remained after 18 days; supplementation resulted in disappearence of 70 and >75% PAN after 2 days (half life: 1.2 days) and complete disappearence after 18 days; abiotic elimination from sterile sewage was 20%. Lake water: after a lag period of 5 days nearly 50% of the initial test substance disappeared within 10 days (abiotic elimination from sterile water: 10 %); supplementation enhanced degradation.
Source	:	Bayer AG Leverkusen
Test condition	:	temperature 21+/-1 degree C; dark; shaken; unsupplemented or supplemented with nutrient broth or yeast extract.

18.12.2003 (14) (7)

Type	:	aerobic
Inoculum	:	other
Concentration	:	2 mg/l related to Test substance related to
Method	:	other: batch tests with primary domestic sewage effluent and lake water; radioassay; 14CO2-analysis
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Sewage effluent: after 15 days ca. 13%, after 35 days 21% 14C-PAN were mineralized to 14CO2 (supplemented samples: 27% after 35 days).

Lake water: 4.2% mineralization after 13 days (supplemented samples: 9.7% after 11 days).

Source : Bayer AG Leverkusen
Test condition : temperature 21+/-1 degree C; dark; shaken; unsupplemented or supplemented with nutrient broth or yeast extract.

18.12.2003 (14) (7)

Type :
Inoculum : activated sludge
Concentration : 100 mg/l related to
related to
Contact time :
Degradation : 0 (±) % after 14 day(s)
Result : under test conditions no biodegradation observed
Deg. product :
Method : other: according to OECD Guide-line 301 C
Year : 1981
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Method : "Biodegradation test of chemical substance by microorganisms etc." stipulated in the order Prescribing the Items of the Test Relating to the New Chemical Substance (1974, Order of the Prime Minister, the Minister of Health and Welfare, the MITI No. 1). This guideline corresponds to "301C, Ready Biodegradability: Modified MITI Test I" stipulated in the OECD Guidilines for Testing of Chemicals (May 12, 1981).
Source : Bayer AG Leverkusen
Test condition : concentration related to BOD
sludge concentration: 30 mg/l

18.12.2003 (6)

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

Species : Cyprinus carpio (Fish, fresh water)
Exposure period : 56 day(s) at 25 °C
Concentration :
Elimination :
Method : other: according to OECD Guide-line 305 C
Year : 1981
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Method : "Bioaccumulation test of chemical substance in fish and shellfish" stipulated in the order Prescribing the Items of the Test Relating to the New Chemical Substance (1974, Order of the Prime Minister, the Minister of Health and Welfare, the MITI No. 1). This guideline corresponds to "305C, Bioaccumalation: Degree of Bioconcentration in Fish" stipulated in the OECD Guidelines for Testing of Chemicals (May 12, 1981).
Remark : lipid content: 5.4 % (average)
Result : concentration (mg/l) BCF
0.1 427-2730
0.01 889-2490
Source : Bayer AG Leverkusen

18.12.2003 (6)

Species	:	Lepomis macrochirus (Fish, fresh water)
Exposure period	:	10 day(s) at 20 °C
Concentration	:	.03 mg/l
Elimination	:	yes
Method	:	other: flow-through exposure to ^{14}C-PAN
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	BCF based on total 14C residues were 1111 for whole fish, 627 for edible fish and 3820 for viscera; BCF based on PAN were 600 for whole fish, 227 for edible fish and 1424 for viscera.
Source	:	Bayer AG Leverkusen
Test condition	:	acetone as solvent

18.12.2003 (7)

Species	:	Lepomis macrochirus (Fish, fresh water)
Exposure period	:	48 hour(s) at 20 °C
Concentration	:	.02 mg/l
Elimination	:	yes
Method	:	other: static exposure to ^{14}C-PAN
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	BCF after 48 hours: viscera: 4000 head: 400 edible fish: 200
Source	:	Bayer AG Leverkusen
Test condition	:	methanol as solvent

18.12.2003 (7)

Species	:	Lepomis macrochirus (Fish, fresh water)
Exposure period	:	at 20 °C
Concentration	:	.2 mg/l
Elimination	:	yes
Method	:	other: static exposure to ^{14}C-PAN
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	BCF after: 48 hours 5 days viscera: 2548 2141 head: 644 233 edible fish: 346 124 50 % depuration within 6 - 10 h after transfer to clean flowing water.
Source	:	Bayer AG Leverkusen
Test condition	:	methanol as solvent

18.12.2003 (7)

Species	:	other: Daphnia magna
Exposure period	:	72 hour(s) at °C
Concentration	:	40 µg/l
BCF	:	637
Elimination	:	yes
Method	:	other: static exposure to ^{14}C-PAN
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4

Result : Elimination rate was estimated to be 0.016/h
Source : Bayer AG Leverkusen
18.12.2003 (7)

3.8 ADDITIONAL REMARKS

Remark : In degradation tests with lake water a diethylether extract containing two metabolites of PAN was analyzed after 10 days of incubation; a dihydroxy derivative and N-acetyl-PAN were identified, indicating hydroxylation and ring cleavage.
Source : Bayer AG Leverkusen
Test substance : as prescribed by 1.1 - 1.4
18.12.2003 (7)

Remark : After 8 days of exposure to ^{14}C-PAN 60 % of the applied radioactivity was detected in the methanol extract of Lepomis macrochirus; three metabolites were found (on hydroxy derivative).
Source : Bayer AG Leverkusen
Test substance : as prescribed by 1.1 - 1.4
24.02.1994 (7)

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	:	other: static or semistatic
Species	:	Oryzias latipes (Fish, fresh water)
Exposure period	:	48 hour(s)
Unit	:	mg/l
LC50	:	7.9
Limit test	:	
Analytical monitoring	:	no data
Method	:	other: according to Japanese Industrial Standard (JIS K 0102-1986-71) "Testing methods for industrial waste water"
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Bayer AG Leverkusen
Test condition	:	25 ± 2 degree C; renewal of test water, at every 8-16 h
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards
Flag	:	Critical study for SIDS endpoint

18.12.2003 (6)

Type	:	flow through
Species	:	Lepomis macrochirus (Fish, fresh water)
Exposure period	:	8 day(s)
Unit	:	mg/l
NOEC	:	.18 - .24
LC50	:	.46 - .48
Limit test	:	
Analytical monitoring	:	yes
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Test 1: LC50: 0.46 mg/l; NOEC: 0.18 mg/l Test 2: LC50: 0.48 mg/l; NOEC: 0.24 mg/l
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (7)

Type	:	flow through
Species	:	Oncorhynchus mykiss (Fish, fresh water)
Exposure period	:	8 day(s)
Unit	:	mg/l
NOEC	:	.11
LC50	:	.3
Limit test	:	
Analytical monitoring	:	yes
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (7)

Type	:	semistatic
Species	:	Lepomis macrochirus (Fish, fresh water)
Exposure period	:	8 day(s)
Unit	:	mg/l
NOEC	:	.22
LC50	:	.52
Limit test	:	
Analytical monitoring	:	yes
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (7)

Type	:	semistatic
Species	:	Oncorhynchus mykiss (Fish, fresh water)
Exposure period	:	4 day(s)
Unit	:	mg/l
NOEC	:	.22
LC50	:	.44
Limit test	:	
Analytical monitoring	:	yes
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (7)

Type	:	static
Species	:	Lepomis macrochirus (Fish, fresh water)
Exposure period	:	24 hour(s)
Unit	:	mg/l
NOEC	:	> 5
Limit test	:	
Analytical monitoring	:	no data
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	only one concentration tested
Source	:	Bayer AG Leverkusen
Test condition	:	temperature 13 degree C; pH 7.5-8.2; acetone or ethanol as solvent

18.12.2003 (20)

Type	:	static
Species	:	Oncorhynchus mykiss (Fish, fresh water)
Exposure period	:	24 hour(s)
Unit	:	mg/l
NOEC	:	> 5
Limit test	:	
Analytical monitoring	:	no data

Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	only one concentration tested
Source	:	Bayer AG Leverkusen
Test condition	:	temperature 13 degree C; pH 7.5-8.2; acetone or ethanol as solvent

18.12.2003 (20)

Type	:	static
Species	:	Petromyzon marinus
Exposure period	:	24 hour(s)
Unit	:	mg/l
NOEC	:	> 5
Limit test	:	
Analytical monitoring	:	no data
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	larvae tested only one concentration tested
Source	:	Bayer AG Leverkusen
Test condition	:	temperature 13 degree C; pH 7.5-8.2; acetone or ethanol as solvent

18.12.2003 (20)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type	:	semistatic
Species	:	Daphnia magna (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	mg/l
NOEC	:	.36
EC50	:	.68
Analytical monitoring	:	yes
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Bayer AG Leverkusen
Test condition	:	first instar (12±12 h); hard water; ethanol as solvent.
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards
Flag	:	Critical study for SIDS endpoint

18.12.2003 (7)

Type	:	static
Species	:	Daphnia magna (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	mg/l
NOEC	:	.13
EC50	:	.3
Analytical monitoring	:	yes
Method	:	other
Year	:	
GLP	:	no data

Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Bayer AG Leverkusen
Test condition	:	first instar (12±12 h); soft water; ethanol as solvent.
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (7)

Type	:	static
Species	:	Daphnia magna (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	mg/l
NOEC	:	.22
EC50	:	.68
Analytical monitoring	:	yes
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Bayer AG Leverkusen
Test condition	:	adults (7±1 days); soft water; ethanol as solvent.
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (7)

Type	:	semistatic
Species	:	Daphnia magna (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	mg/l
NOEC	:	.22
EC50	:	.67
Analytical monitoring	:	yes
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Bayer AG Leverkusen
Test condition	:	first instar (12±12 h); soft water; ethanol as solvent.
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (7)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

Type	:	aquatic
Species	:	activated sludge
Exposure period	:	3 hour(s)
Unit	:	mg/l
EC50	:	> 10000
Analytical monitoring	:	no
Method	:	OECD Guide-line 209 "Activated Sludge, Respiration Inhibition Test"
Year	:	1984
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

Remark	:	Application of 10g PAN/l was followed by 16 % decrease in sludge respiration rate.
Source	:	Bayer AG Leverkusen
Reliability	:	(1) valid without restriction GLP guideline study

18.12.2003 (3)

Type	:	aquatic
Species	:	Tetrahymena pyriformis (Protozoa)
Exposure period	:	48 hour(s)
Unit	:	mg/l
EC50	:	2
Analytical monitoring	:	no data
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	other TS

Source	:	Bayer AG Leverkusen
Test condition	:	static; 28 degree C; pH 6.8; dark; acetone as solvent
Test substance	:	technical PAN-mixture (Neozone A)

18.12.2003 (21)

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Species	:	Daphnia magna (Crustacea)
Endpoint	:	mortality
Exposure period	:	21 day(s)
Unit	:	mg/l
NOEC	:	.02
EC50	:	.06
Analytical monitoring	:	yes
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4

Result	:	after 2 d after 21 d NOEC (mg/l) 0.16 0.02 LC50 (mg/l) >0.16 0.06
Source	:	Bayer AG Leverkusen
Test condition	:	semistatic; first instar (12±12 h); hard water; ethanol as solvent; renewal of water: 3x/week; feed concentration: 30 mg/l
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (7)

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

Remark	:	Toxicity to amphibia: 48 h LC50 for larvae of the leopard frog Xenopus laevis was 2.3 mg/l (confidence limit: 1.96 - 2.76 mg/l); exposure of Xenopus laevis embryos to >5.2 mg/l was teratogenic in 23% of the surviving animals (73%) and > 6.2 mg/l was lethal in 79%; exposure from blastula stages to hatching resulted in an EC50 of 4.57 mg/l (confidence limit: 3.39 - 5.3 mg/l) for teratogenic effects, when exposed during neurulation. Exposure of 5 mg/l or greater (no details given) to larvae of the South African clawed toad Rana pipiens for 24 h had no toxic effect, while 48 h exposure caused 100% mortality.
Source	:	Bayer AG Leverkusen
Test substance	:	no data

18.12.2003 (9) (22) (23) (24) (25)

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

5.1.1 ACUTE ORAL TOXICITY

Type : LD50
Value : > 5000 mg/kg bw
Species : rat
Strain :
Sex : male/female
Number of animals :
Vehicle :
Doses :
Method : other
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Remark : 2/10 females and 0/10 males died at tested concentration of 5,000 mg/kg; signs of reduced general state.
Source : Bayer AG Leverkusen
Reliability : (2) valid with restrictions
Meets generally accepted scientific standards
Flag : Critical study for SIDS endpoint
18.12.2003 (26)

Type : LD50
Value : 200 - 2000 mg/kg bw
Species : rat
Strain :
Sex : male/female
Number of animals :
Vehicle :
Doses :
Method : other
Year :
GLP : no data
Test substance : no data

Result :

Conc.	Mortality males	Mortality females
200 mg/kg bw	0/3	0/3
2000 mg/kg bw	1/3	3/3

Source : Bayer AG Leverkusen
18.12.2003 (27)

Type : LD50
Value : = 2380 mg/kg bw
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Method : other
Year :
GLP : no data
Test substance : no data

Source : Bayer AG Leverkusen
18.12.2003 (28)

Type : LD50
Value : = 1630 mg/kg bw
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Method : other
Year :
GLP : no data
Test substance :

Source : Bayer AG Leverkusen
18.12.2003 (29)

Type : LD50
Value : = 1625 mg/kg bw
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Method : other
Year :
GLP : no data
Test substance :

Source : Bayer AG Leverkusen
18.12.2003 (30)

Type : LD50
Value : = 1231 mg/kg bw
Species : mouse
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Method : other
Year :
GLP : no data
Test substance :

Source : Bayer AG Leverkusen
18.12.2003 (30)

Type : LD0
Value : = 500 mg/kg bw
Species : mouse
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Method : other
Year :

GLP	:	no data
Test substance	:	
Remark	:	only 1 mouse was used
Source	:	Bayer AG Leverkusen
Reliability	:	(3) invalid Significant methodological deficiencies

18.12.2003 (31)

Type	:	other
Value	:	= 4000 mg/kg bw
Species	:	rabbit
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	Animals (sex and number: no data) died within 72 h.
Source	:	Bayer AG Leverkusen
Reliability	:	(4) not assignable Secondary literature.

18.12.2003 (32)

Type	:	other
Value	:	= 4000 mg/kg bw
Species	:	guinea pig
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	Animals (sex and number: no data) died within 72 h.
Source	:	Bayer AG Leverkusen
Reliability	:	(4) not assignable Secondary literature.

18.12.2003 (32)

5.1.2 ACUTE INHALATION TOXICITY

Type	:	other
Value	:	
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	6
Vehicle	:	
Doses	:	substantially saturated vapor
Exposure time	:	8 hour(s)
Method	:	other
Year	:	

GLP : no data
Test substance : no data

Result : Mortality: 0/6
Source : Bayer AG Leverkusen
18.12.2003 (28)

5.1.3 ACUTE DERMAL TOXICITY

Type : LD50
Value : > 5000 mg/kg bw
Species : rabbit
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Method : other
Year :
GLP : no data
Test substance : no data

Result :

Conc.	Mortality
2000 mg/kg	0/2
8000 mg/kg	1/5

Source : Bayer AG Leverkusen
18.12.2003 (28)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

Type : other
Value : = 219 mg/kg bw
Species : mouse
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Route of admin. : i.p.
Exposure time :
Method : other
Year :
GLP : no data
Test substance : no data

Remark : A single injection of 219 mg/kg (1 mM/kg) induced methemoglobinemia.
Source : Bayer AG Leverkusen
18.12.2003 (33)

Type : LD0
Value : = 500 mg/kg bw
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Doses :

Route of admin.	:	s.c.
Exposure time	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	
Remark	:	only 1 rat was used
Source	:	Bayer AG Leverkusen
Reliability	:	(3) invalid Significant methodological deficiencies

18.12.2003 (34)

Type	:	LD0
Value	:	= 200 mg/kg bw
Species	:	rabbit
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Route of admin.	:	s.c.
Exposure time	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	
Remark	:	only 2 rabbits were used
Source	:	Bayer AG Leverkusen
Reliability	:	(3) invalid Significant methodological deficiencies

18.12.2003 (34)

5.2.1 SKIN IRRITATION

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	slightly irritating
Classification	:	
Method	:	Draize Test
Year	:	1944
GLP	:	no data
Test substance	:	no data
Source	:	Bayer AG Leverkusen

18.12.2003 (35)

Species	:	human
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	

Result	:	not irritating
Classification	:	
Method	:	other: see remarks
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	Application of an aqueous paste, a powder or an oily preparation to the skin of human volunteers caused no irritation or sensitization.
Source	:	Bayer AG Leverkusen

18.12.2003 (34) (36)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	5
Vehicle	:	
PDII	:	
Result	:	slightly irritating
Classification	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	application as a 50 % solution in Carbowax PEG 400 onto the clipped, uncovered intact skin of 5 rabbits.
Source	:	Bayer AG Leverkusen

18.12.2003 (28)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	not irritating
Classification	:	
Method	:	Draize Test
Year	:	1944
GLP	:	no data
Test substance	:	no data
Source	:	Bayer AG Leverkusen
Reliability	:	(4) not assignable Secondary literature.

18.12.2003 (30)

Species	:	rabbit
Remark	:	repeated application of a PAN-solution (5 %) onto the ear: 3/3 animals showed slight redness (for further information see chap. 5.4)
Source	:	Bayer AG Leverkusen

18.12.2003 (34)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	4 hour(s)

Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	
Classification	:	
Method	:	other: rabbit test as desribed in 21 CFR paragraph 191.11
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	no further information available
Result	:	0/6 rabbits with necrosis
Source	:	Bayer AG Leverkusen
Reliability	:	(3) invalid Documentation insufficient for assessment.

18.12.2003 (37)

5.2.2 EYE IRRITATION

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure time	:	
Comment	:	
Number of animals	:	
Vehicle	:	
Result	:	not irritating
Classification	:	
Method	:	OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year	:	1981
GLP	:	no data
Test substance	:	other TS: commercial grade
Source	:	Bayer AG Leverkusen
Reliability	:	(1) valid without restriction Guideline study

18.12.2003 (38)

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure time	:	
Comment	:	
Number of animals	:	
Vehicle	:	
Result	:	not irritating
Classification	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	instillation as ground powder or 0.5 ml of a 50 % solution in Carbowax PEG 400
Source	:	Bayer AG Leverkusen

18.12.2003 (28)

Species	:	rabbit
Concentration	:	
Dose	:	

Exposure time	:	
Comment	:	
Number of animals	:	
Vehicle	:	
Result	:	slightly irritating
Classification	:	
Method	:	other: Fed. Reg. 28 (119), 5582
Year	:	1963
GLP	:	no data
Test substance	:	no data
Source	:	Bayer AG Leverkusen

18.12.2003 (39)

5.3 SENSITIZATION

Type	:	Guinea pig maximization test
Species	:	guinea pig
Number of animals	:	
Vehicle	:	
Result	:	sensitizing
Classification	:	
Method	:	OECD Guide-line 406 "Skin Sensitization"
Year	:	1981
GLP	:	no data
Test substance	:	other TS: commercial grade
Source	:	Bayer AG Leverkusen
Reliability	:	(1) valid without restriction Guideline study

18.12.2003 (40)

Type	:	Guinea pig maximization test
Species	:	guinea pig
Number of animals	:	
Vehicle	:	
Result	:	sensitizing
Classification	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Source	:	Bayer AG Leverkusen

18.12.2003 (41)

Type	:	Patch-Test
Species	:	human
Number of animals	:	
Vehicle	:	
Result	:	
Classification	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	1/24 patients with contact dermatitis reacted positive to 1% PAN and also to mercaptobenzothiazole.
Source	:	Bayer AG Leverkusen

18.12.2003 (42)

Type	:	Patch-Test
Species	:	human
Number of animals	:	
Vehicle	:	
Result	:	
Classification	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	Positive reaction in one patient with contact dermatitis tested with PAN.
Source	:	Bayer AG Leverkusen

18.12.2003 (41)

Type	:	Patch-Test
Species	:	human
Number of animals	:	
Vehicle	:	
Result	:	
Classification	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	1/15 patients with contact dermatitis reacted positive to PAN (unknown concentration) and other substances used in rubber industry.
Source	:	Bayer AG Leverkusen

18.12.2003 (43)

Type	:	Patch-Test
Species	:	human
Number of animals	:	
Vehicle	:	
Result	:	
Classification	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	1/6 patients with contact dermatitis reacted positive to 1% PAN and other substances used in rubber industry.
Source	:	Bayer AG Leverkusen

18.12.2003 (44) (45)

Type	:	Patch-Test
Species	:	human
Number of animals	:	
Vehicle	:	
Result	:	
Classification	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data

Remark	:	None of 13 tested persons with contact dermatitis reacted positive to 1 % PAN.
Source	:	Bayer AG Leverkusen

18.12.2003 (46)

Type	:	Patch-Test
Species	:	human
Number of animals	:	
Vehicle	:	
Result	:	
Classification	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	1/2 patients with contact dermatitis reacted positive to 0.5 and 1% PAN and other substances of industrial greases.
Source	:	Bayer AG Leverkusen

18.12.2003 (47)

Type	:	Patch-Test
Species	:	human
Number of animals	:	
Vehicle	:	
Result	:	
Classification	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	2/3 patients with contact dermatitis reacted positive to 1% PAN and other grease compounds.
Source	:	Bayer AG Leverkusen

18.12.2003 (48)

Type	:	other
Species	:	guinea pig
Number of animals	:	
Vehicle	:	
Result	:	not sensitizing
Classification	:	
Method	:	other: modified Landsteiner Guinea pig sensitization test
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	no further details available
Source	:	Bayer AG Leverkusen
Reliability	:	(4) not assignable Secondary literature.

18.12.2003 (30)

5.4 REPEATED DOSE TOXICITY

Type	:	
Species	:	dog
Sex	:	no data
Strain	:	no data

Route of admin.	:	oral feed
Exposure period	:	36-42 months
Frequency of treatm.	:	5 days/week
Post exposure period	:	no data
Doses	:	290 mg/kg
Control group	:	no data specified
NOAEL	:	= 290 mg/kg
Method	:	other
Year	:	
GLP	:	no
Test substance	:	no data

Remark	:	three animals tested
Result	:	no signs of toxicity
Source	:	Bayer AG Leverkusen

18.12.2003 (49) (50) (36)

Type	:	
Species	:	rabbit
Sex	:	male/female
Strain	:	no data
Route of admin.	:	s.c.
Exposure period	:	7 weeks
Frequency of treatm.	:	42 applications in 7 weeks
Post exposure period	:	
Doses	:	50 mg/kg
Control group	:	no data specified
Method	:	other
Year	:	
GLP	:	no
Test substance	:	

Remark	:	one animal/sex tested
Result	:	no clinical signs in both sexes; after necropsy at 3 months only in the male slight fatty liver degeneration
Source	:	Bayer AG Leverkusen
Reliability	:	(3) invalid Significant methodological deficiencies

18.12.2003 (34)

Type	:	
Species	:	rabbit
Sex	:	female
Strain	:	no data
Route of admin.	:	s.c.
Exposure period	:	7 weeks
Frequency of treatm.	:	42 applications in 7 weeks
Post exposure period	:	
Doses	:	200 mg/kg
Control group	:	no data specified
Method	:	other
Year	:	
GLP	:	no
Test substance	:	

Remark	:	two animals tested
Result	:	no specific clinical signs; necropsy after 3 months revealed signs of slight fatty liver degeneration and in one animal single connective tissue proliferations
Source	:	Bayer AG Leverkusen
Reliability	:	(3) invalid Significant methodological deficiencies

18.12.2003 (34)

Type	:	
Species	:	rabbit
Sex	:	male
Strain	:	no data
Route of admin.	:	dermal
Exposure period	:	6 weeks
Frequency of treatm.	:	35 applications in 6 weeks
Post exposure period	:	no data
Doses	:	5 % solution
Control group	:	no data specified
Method	:	other
Year	:	
GLP	:	no
Test substance	:	
Remark	:	two animals tested
Result	:	slight irritation of treated ears
Source	:	Bayer AG Leverkusen
Reliability	:	(3) invalid Significant methodological deficiencies

18.12.2003 (34)

Type	:	
Species	:	rabbit
Sex	:	male
Strain	:	no data
Route of admin.	:	dermal
Exposure period	:	5 weeks
Frequency of treatm.	:	28 applications in 5 weeks
Post exposure period	:	
Doses	:	5 % solution
Control group	:	no data specified
Method	:	other
Year	:	
GLP	:	no
Test substance	:	
Remark	:	one animal tested
Result	:	slight irritation of treated ears, proteinuria, anorexia, died 5 days after 27th application, fatty liver degeneration
Source	:	Bayer AG Leverkusen
Reliability	:	(3) invalid Significant methodological deficiencies

18.12.2003 (34)

Type	:	
Species	:	rabbit
Sex	:	female
Strain	:	no data
Route of admin.	:	oral feed
Exposure period	:	6 weeks
Frequency of treatm.	:	5 days/week
Post exposure period	:	no
Doses	:	200 mg/kg
Control group	:	no data specified
Method	:	other
Year	:	
GLP	:	no
Test substance	:	

Remark	:	one animal tested
Result	:	diarrhea, proteinuria, death at the end of application, slight "kidney irritation", strong fatty liver degeneration
Source	:	Bayer AG Leverkusen
Reliability	:	(3) invalid Significant methodological deficiencies

18.12.2003 (34)

Type	:	
Species	:	rabbit
Sex	:	female
Strain	:	no data
Route of admin.	:	oral feed
Exposure period	:	5 days
Frequency of treatm.	:	daily
Post exposure period	:	no data
Doses	:	200 mg/kg
Control group	:	no data specified
Method	:	other
Year	:	
GLP	:	no
Test substance	:	

Remark	:	one animal tested
Result	:	diarrhea, anorexia, died at day 5, slight "kidney irritation", fatty liver degeneration
Source	:	Bayer AG Leverkusen
Reliability	:	(3) invalid Significant methodological deficiencies

18.12.2003 (34)

Type	:	
Species	:	rabbit
Sex	:	no data
Strain	:	no data
Route of admin.	:	inhalation
Exposure period	:	24 h/d for several months
Frequency of treatm.	:	daily with interruptions
Post exposure period	:	no data
Doses	:	about 100 mg/d were evaporated
Control group	:	yes
Method	:	other
Year	:	
GLP	:	no
Test substance	:	no data

Remark	:	four animals tested
Result	:	After 3-4 months signs of progressive anemia, leukopenia, lymphocytosis, pneumonia, abscess forming processes in the lung, fatty liver degeneration, nephritis/nephrosis, death within 6-24 months.
Source	:	Bayer AG Leverkusen
Reliability	:	(3) invalid Significant methodological deficiencies

18.12.2003 (51)

Type	:	
Species	:	mouse
Sex	:	no data
Strain	:	no data
Route of admin.	:	i.p.
Exposure period	:	9 days
Frequency of treatm.	:	daily

Post exposure period	:	
Doses	:	109.5 mg/kg (0.5 mM)
Control group	:	yes
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Result	:	No induction of methemoglobinemia (48 h after end of treatment)
Source	:	Bayer AG Leverkusen
Reliability	:	(4) not assignable Documentation insufficient for assessment.

18.12.2003 (33)

Type	:	
Species	:	mouse
Sex	:	no data
Strain	:	no data
Route of admin.	:	i.p.
Exposure period	:	3 days
Frequency of treatm.	:	daily
Post exposure period	:	
Doses	:	219 mg/kg (1 mM)
Control group	:	yes
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Result	:	Induction of methemoglobinemia (48 h after end of treatment)
Source	:	Bayer AG Leverkusen
Reliability	:	(4) not assignable Documentation insufficient for assessment.

18.12.2003 (33)

Type	:	
Species	:	mouse
Sex	:	male
Strain	:	no data
Route of admin.	:	oral feed
Exposure period	:	3 days
Frequency of treatm.	:	daily
Post exposure period	:	no data
Doses	:	1000 mg/kg
Control group	:	no data specified
Method	:	other
Year	:	
GLP	:	no
Test substance	:	
Remark	:	one animal tested
Result	:	found dead at day 11
Source	:	Bayer AG Leverkusen
Reliability	:	(3) invalid Significant methodological deficiencies

18.12.2003 (34)

Type	:	
Species	:	rat
Sex	:	female
Strain	:	no data

Route of admin.	:	s.c.
Exposure period	:	3 days
Frequency of treatm.	:	daily
Post exposure period	:	no data
Doses	:	1000 mg/kg
Control group	:	no data specified
Method	:	other
Year	:	
GLP	:	no
Test substance	:	
Remark	:	one animal tested
Result	:	no signs of toxicity
Source	:	Bayer AG Leverkusen
Reliability	:	(3) invalid Significant methodological deficiencies

18.12.2003 (34)

5.5 GENETIC TOXICITY 'IN VITRO'

Type	:	Ames test
System of testing	:	S. typhimurium TA 97, 98, 100, 1535, 1537
Test concentration	:	0.3-666 µg/plate
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other: similar to EPA OPPTS 870.5265
Year	:	
GLP	:	no data
Test substance	:	other TS: N-phenyl-1-Naphthalenamine, CAS# 90-30-2; purity not noted
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards
Flag	:	Critical study for SIDS endpoint

18.12.2003 (52)

Type	:	Cytogenetic assay
System of testing	:	CHO cells
Test concentration	:	2.99-29.9 µg/ml (non-activated); 1.49-19.9 µg/ml (activated)
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	other TS: N-phenyl-1-Naphthalenamine, CAS# 90-30-2; purity not noted
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards
Flag	:	Critical study for SIDS endpoint

18.12.2003 (53) (54)

Type	:	Cytogenetic assay
System of testing	:	CHL cells
Test concentration	:	30 µg/ml (non-activated); 15.6 µg/ml (activated)
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative

Method	:	other
Year	:	
GLP	:	no data
Test substance	:	other TS: N-phenyl-1-Naphthalenamine, CAS# 90-30-2; purity not noted
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (55)

Type	:	Bacterial gene mutation assay
System of testing	:	E. coli WP2
Test concentration	:	0.01-1000 µg/plate
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Source	:	Bayer AG Leverkusen

18.12.2003 (56)

Type	:	Gene mutation in Saccharomyces cerevisiae
System of testing	:	S. cerevisiae D4
Test concentration	:	0.5-500 µl/plate
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (57) (58)

Type	:	Mouse lymphoma assay
System of testing	:	L5178Y cells
Test concentration	:	0.5-25 µg/ml (non-activated); 0.005-0.1 µg/ml (activated)
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (57) (58)

Type	:	Sister chromatid exchange assay
System of testing	:	CHO cells
Test concentration	:	1.82-18.2 µg/ml (non-activated); 0.805-19.9 µg/ml (activated)
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	ambiguous

Method	:	other
Year	:	
GLP	:	no data
Test substance	:	
Remark	:	negative without activation; with activation in two trials tested: weak positive and positive resp.
Source	:	Bayer AG Leverkusen
18.12.2003		(59) (54)
Type	:	Unscheduled DNA synthesis
System of testing	:	WI-38 cells
Test concentration	:	5-50 µg/ml
Cycotoxic concentr.	:	100 µg/ml (wihout activation)
Metabolic activation	:	with and without
Result	:	ambiguous
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	Repeated positive results in non-activated but not in activated tests; lack of a clear dose-related response reduced confidence in the effect
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards
18.12.2003		(57) (58)
Type	:	Ames test
System of testing	:	S. typhimurium TA 98, 100, 1535, 1537, 1538
Test concentration	:	no data
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Source	:	Bayer AG Leverkusen
18.12.2003		(60)
Type	:	Bacterial gene mutation assay
System of testing	:	S. typhimurium TA 98, 100, 1535, 1537, 1538
Test concentration	:	0.5-500 µl/plate
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards
18.12.2003		(57) (58)
Type	:	Bacterial gene mutation assay
System of testing	:	S. typhimurium TA 98, 100, 1535, 1537
Test concentration	:	0.01-1000 µg/plate

Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data

Source	:	Bayer AG Leverkusen

18.12.2003 (56)

Type	:	Bacterial gene mutation assay
System of testing	:	E. coli WP2 uvrA-
Test concentration	:	0.5-500 µl/plate
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data

Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards

18.12.2003 (57) (58)

5.6 GENETIC TOXICITY 'IN VIVO'

Type	:	Dominant lethal assay
Species	:	mouse
Sex	:	male
Strain	:	ICR
Route of admin.	:	i.p.
Exposure period	:	5 days
Doses	:	50, 166 or 500 mg/kg
Result	:	negative
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data

Source	:	Bayer AG Leverkusen
Reliability	:	(2) valid with restrictions Meets generally accepted scientific standards
Flag	:	Critical study for SIDS endpoint

18.12.2003 (57) (58)

5.7 CARCINOGENICITY

Species	:	dog
Sex	:	no data
Strain	:	no data
Route of admin.	:	oral feed
Exposure period	:	36-42 months
Frequency of treatm.	:	5 days/week
Post exposure period	:	no
Doses	:	290 mg/kg

Result	:	
Control group	:	no data specified
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	three animals tested
Result	:	negative
Source	:	Bayer AG Leverkusen

25.02.1994 (61) (62) (63)

Species	:	mouse
Sex	:	male
Strain	:	other: see remarks
Route of admin.	:	s.c.
Exposure period	:	see remarks
Frequency of treatm.	:	see remarks
Post exposure period	:	
Doses	:	5.3 and 16 mg pure PAN; 16 mg technical PAN
Result	:	
Control group	:	yes, concurrent vehicle
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	male ICR mice were used for experiment 1 (E.1); male TA-1 mice for experiment 2 (E.2, in some groups the left kidney was removed) E.1 group 2: 16 mg techn. PAN, 3x/week, 295 days E.1 group 3: 16 mg pure PAN, 3x/week, 291 days E.1 group 4: 5.3 mg pure PAN, 3x/week, 290 days E.2 group 1: 16 mg pure PAN, 2x/week, 273 days (nephrectomy) E.2 group 2: 16 mg techn. PAN, 2x/week, 262 days (nephrectomy) E.2 group 3: 16 mg techn. PAN, 2x/week, 273 days
Result	:	In ICR mice a total dose of 432 mg technical PAN led to an increase in lung carcinomas and hemangiosarcaomas, the same dose pure PAN increased the fequency of kidney hemangiosarcomas and a total dose of 135 mg pure PAN elevated the incidence of lung carcinomas and the sum of all hemangiosarcomas; no dose-dependency was given for the incidence of all malignancies. In nephrectomized TA-1 mice a total dose of 328 mg pure and technical PAN increased the frequency of kidney hemangiosarcomas and the comparison with non-nephrectomized mice indicated that nephrectomy promoted the susceptibility of mice receiving the technical product.
Source	:	Bayer AG Leverkusen

18.12.2003 (64)

5.8.1 TOXICITY TO FERTILITY

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

Remark : An epidemiologic cohort study in an engineering company was prompted by the observation of three cases of cancer; it revealed several more cases among women who wrapped bearing rings covered with antirust oil, i.e. 12 cases versus 3.9 expected. The 12 tumor sites were situated in different organs including the uterus, ovaries, breast, thyroid, brain, colon and bladder. In men no significant differences were noted.
The authors concluded that PAN or its nitroso derivative was likely the causative agent, if the increased incidence was not a random phenomenon.

Source : Bayer AG Leverkusen
18.12.2003 (65)

5.11 ADDITIONAL REMARKS

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

8.1 METHODS HANDLING AND STORING

8.2 FIRE GUIDANCE

8.3 EMERGENCY MEASURES

8.4 POSSIB. OF RENDERING SUBST. HARMLESS

8.5 WASTE MANAGEMENT

8.6 SIDE-EFFECTS DETECTION

8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

8.8 REACTIVITY TOWARDS CONTAINER MATERIAL

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10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT